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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,992	04/05/2001	Nurhan Pinar Tutuncu	2280.2660	3697

5514 7590 06/14/2005

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,992

Applicant(s)

TUTUNCU ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-8, 10-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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DETAILED ACTION

Receipt of Amendments and Arguments received on March 4, 2004 is acknowledged. Claims 1-8 and 10-25 are pending in this application. Claims 9 and 11 stand cancelled.

Withdrawn Rejections

The rejection of claims 6 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the arguments of 3/4/05.

The rejection of claims 1-8, 10, 13-14, 17, 20, and 22-26 under 35 U.S.C. 102(b) as being anticipated by EP 0150934 to Cherukuri et al withdrawn in view of the amendments of 3/4/05.

The rejection of claims 1, 6, 8, 10-13, 17, 20, 23-24, and 26-27 under 35 U.S.C. 102(b) as being anticipated by US patent 5,284,659 to Cherukuri et al withdrawn in view of the amendments of 3/4/05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3, 6-8, 10, 15-18, and 20-25 under 35 U.S.C. 102(e) as being anticipated by US patent 6,231,900 to Hanke is maintained.

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Hanke discloses a confectionary product for soothing core through and relief of symptoms associated with cough and cold. The product is administered as a throat drop or lozenge, which releases the actives upon sucking in the oral cavity. See abstract and column 1, lines 10-20. Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition. The cooling agent taught is as any agent that provides a physiological cooling effect. See column 2, lines 55-57. The flavoring composition can be chosen from synthetic flavoring liquid or oils. Flavoring liquid include cinnamon oil, artificial, natural, or synthetic fruit flavors, i.e. citrus oil including lemon, orange, pineapple, etc, and fruit essences in an amount of 0.1-4% See column 7, lines 5-26. Further, claim 14 is directed to utilizing citrus oil. Note that the citrus oil reads on applicant's "lipid" in the oral comfort region.

The examples utilize a sweetened gelatine mixture comprising 7.1% gelatine, 26.1% sucrose, 44.6% glucose syrup, and 22.2 water. Example 1 discloses the two separate compositions wherein A contains 97.8% of a sweetened gelatin mixture, 1.4% citric acid, and 0.6% of an orange flavor. Composition B contains 99% of a sweetened gelatin mixture, 0.7% citric acid (acidulent), and 0.1 menthol (cooling compound). Hanke discloses the use of a mold in which the respective composition is placed and each composition has a surface on the exterior of the product. The amount of sucrose and glucose in the composition is approximately 69%.

Note that composition A reads on the oral comfort region and composition B reads on the instant salivation region.

With regard to claim 20 directed to a method of treating xerostomia, it is the examiner's position that the preamble is implicitly met since the prior art discloses the instant method steps of administering a confectionary product to the oral cavity containing. Further, the prior art

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discloses the confectionary product relieves throat irritation, which is a symptom of xerostomia.

Therefore, the instant method steps are not distinguishable over the prior art.

Response to Arguments

Applicant argues that the amendment to the claims deleting “proteins” from the Markush group, overcomes the instant rejection.

Applicant's arguments filed 3/4/05 have been fully considered but they are not persuasive. The amendments of 3/4/05 do not overcome prior art since Hanke teaches the use of an orange flavor in composition A. This orange flavor is taught to be a flavor *oil* and thus reads on applicant's broad claim to “lipids” in the oral comfort region. Hanke's composition A reads on the oral comfort region since it contains flavor oil and composition B reads on the salivation region since it contains menthol, a cooling agent, and citric acid. Although citric acid is taught in both composition A and B, the claims are open-ended and the acidulent is required in only one region but may be in both.

For the reasons set forth above, the rejection is maintained.

New Rejection Based on Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-8, 10-11, 15-18, and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,231,900 to Hanke (6231900)

Hanke discloses a confectionary product for soothing sore throat and relief of symptoms associated with cough and cold. The product is administered as a throat drop or lozenge, which releases the actives upon sucking in the oral cavity. See abstract and column 1, lines 10-20. Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition. The cooling agent taught is as any agent that provides a physiological cooling effect. See column 2, lines 55-57. The flavoring composition can be chosen from synthetic flavoring liquid or oils. Flavoring liquid include cinnamon oil, artificial, natural, or synthetic fruit flavors such as citrus oil including lemon, orange, pineapple, etc, in an amount of 0.1-4%. . See column 7, lines 5-26. Further claim 14 is directed to utilizing a flavoring composition that contains citrus oil. The carriers are sugar or sugar-free bases. The sugar base is selected from sucrose, fructose, glucose, or corn syrup and the sugar-free base is selected from sorbitol or xylitol. See column 5, lines 55-63 and column 6, lines 45-50.

The examples utilize a sweetened gelatine mixture comprising 7.1% gelatine, 26.1% sucrose, 44.6% glucose syrup, and 22.2 water. Example 1 discloses the two separate

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compositions wherein A contains 97.8% of a sweetened gelatin mixture, 1.4% citric acid, and 0.6% of an orange flavor. Composition B contains 99% of a sweetened gelatin mixture, 0.7% citric acid (acidulent), and 0.1% menthol (cooling compound). Hanke discloses the use of a mold in which the respective composition is placed and each composition has a surface on the exterior of the product. The amount of sucrose and glucose in the composition is approximately 69%. Note that composition A reads on the oral comfort region and composition B reads on the instant salivation region.

With regard to claims 1-3, 6-8, 15-18, and 20-27, although it is the examiner's position that the orange flavor is orange oil since Hanke makes a distinction between oil and essence, it is unclear if Hanke's orange flavor utilized in the example is in fact, orange oil.

Thus, with regard to claims 1-3, 6-8, 15-18, and 20-27 assuming the orange flavor in example 1 is not orange oil, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Hanke and utilize flavor oil in the composition. One would have been motivated to utilize flavor *oil* since Hanke teaches that the flavor composition (composition A) may contain fruit oil or essence. Therefore, the use of the oil versus fruit essence is *prima facie* obvious.

With regard to claims 4-5, although Hanke does not exemplify a sugar-less base, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Hanke and utilize a sugarless base. One would have been motivated to do so with an expectation of similar results and success since Hanke teaches the carrier may be a sugar or sugarless base. Therefore, the substitution of the exemplified sugar base with the instant sugarless base is *prima facie* obvious.

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With regard to claim 11, although example 1 teaches the flavor oil in the amount of 0.6%, column 7 suggests incorporating the flavor in an amount of 0.1-4%, which overlaps the instant range of 0.1-4%. The manipulation of the concentration of the flavor in view of the guidance provided by Hanke is prima facie obvious.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,231,900 to Hanke (6231900) in view of US patent 6,099,880 to Klacik et al.

As set forth above, Hanke discloses preparation of a confectionary product to relieve cough containing a separate and distinct region for a flavor composition and a cooling composition. Hanke discloses the use of a mold in which the respective compositions are placed. (Note example 1)

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method to be a simple method. See column 1, lines 30-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the Hanke and Klacik et al and utilize a mold with a ridge. One would have been motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge. Therefore, it is obvious to utilize a ridge to further maintain the separation and distinction of each respective region.

Claims 1-6, 8, 10-14, 17, 20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al.

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Cherukuri et al disclose encapsulated flavor with bioadhesive character in pressed mints and confections. The compressed tablet is characterized by discrete phases contained within. See Figure 5 and 6 wherein both phase 1 and 2 have a surface on the exterior of the product. The confectionary compressed tablet is made of a sugar or sugarless base. See column 8, lines 66-67 and column 10, lines 40-45. Sugars taught include sucrose, glucose, dextrose, fructose, and sugar alcohols include sorbitol, mannitol, and xylitol. See column 9, lines 7-21. Emulsifiers (surfactants) are taught in an amount of 2-7%. See column 8, lines 40-55.

Table II, example III discloses a product wherein the shell component contains 97.676% sugar, 0.748 % of a breath deodorant (copper gluconate), 0.234% lubricant, 1.280% flavor beads, 0.062% liquid flavor. This shell region reads on instant “salivation region” since this region contains “copper gluconate” which reads on salt and flavor. The core comprises 40.32% fat encapsulation material of Table I and 59.68% of a diluent. This core region read on instant “oral comfort region”. Table I discloses a fat encapsulation containing 48% partially hydrogenated soybean oil, 5% glycerol monostearate, 10% vegetable oil, 2% flavor oil, and 20% bioadhesive. Cherukuri teaches the diluent may be selected from lactose (sugar), microcrystalline cellulose, starch, talc, sorbitol, mannitol, xylitol, maltitol, xylitol, other sugar alcohols or sugars. See column 8, lines 60-65. Note that this diluent reads on applicant’s confectionary base of the oral comfort region. The tablet is made by mixing each respective composition with the respective components separately and then the core is compressed into the shell portion. See column 10, line 40 to column 11, line 28.

Cherukuri does not specify the diluent, i.e. the use of a sugar or sugar alcohol, utilized in example III.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Cherukuri and utilize a sugar or sugar alcohol as the diluent of choice. One would have been motivated to do so with the expectation of success and similar results since Cherukuri teaches suitable diluents include sugars and sugar alcohols (sugarless base).

With regard to claim 14, the manipulation of the concentration of emulsifier in the core composition of example III is considered to be obvious to one of ordinary skill. The examples utilize a range of 5%, however one would have been motivated to utilize the instant range of 0.5-4% since Cherukuri teaches the emulsifier may be utilized in a range of 2-7%. Therefore, the range taught by Cherukuri overlaps the instant range.

With regard to claim 20 directed to a method of treating xerostomia, it is the examiner's position that the preamble is implicitly met since the prior art discloses the instant method steps of administering a confectionary product to the oral cavity containing. Further, the prior art discloses the confectionary product relieves throat irritation, which is a symptom of xerostomia. Therefore, the instant method steps are not distinguishable over the prior art.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection changing Cherukuri from an anticipatory rejection in view of the amendments to an obviousness rejection. The amendment of 3/4/05 do not overcome Cherukuri as a prior art reference for the reasons discussed above.

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Art of Interest

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patent 4,847,090 to Della Posta et al disclose a confection piece with two or more discrete areas to provide a unique organoleptic response. However, Della Posta does not teach each region having the instant oral comforting components and the instant salivating agents respectively.

Conclusion

None of the claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

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